



Docket No. 5595.210

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Lav et al.
Serial No. : 09/870,392 Examiner: Williams, Catherine Serke
Filed : May 30, 2001 Art Unit: 3763
Title : A Medical Apparatus For Use By A Patient For Medical
Self Treatment of Diabetes

02/15/2006

RULE 132 DECLARATION OF Steffen Lav

I, Steffen Lav, hereby declare as follows:

1. I am an employee of Novo Nordisk A/S, in Bagsvaerd, Denmark. I have worked for Novo Nordisk since 1994 in the field of device development. My current title is Project Manager. I am a joint inventor with respect to the patent application identified above.
2. In 1990, I received a degree in BSc (Mech Eng) from Danish Engineering Academy.
3. It is my understanding that the Examiner in the above application contends that one cannot tell whether the locking means 31 shown in Figures 2-4 "extends from the lancing or is a recessed space (opening) that another member would insert into." Office Action dated 05/05/2005, pp. 2-3. The Examiner also contends that "the quadrilateral shape [of element 31] could depict a 'black box' element that depicts an entirely different intended structure."

Docket No. 5595.210

4. The drawings disclose that, according to several embodiments, the blood glucose monitor BGM 30 includes a convex surface that fits against a concave outer surface of a cap unit 10. The convex surface of the BGM includes a pair of "locking means 31." The specification discloses that the locking means 31 allows the BGM 30 to be removably fitted to the cap 10. P. 6, ll. 22-26.

5. The lancet device 40 has the same convex surface as the BGM 30. The convex surface of the lancet device also contains a pair of locking means 31, which the drawings depict as identical to the locking means 31 of the lancet device. The lancet device 40 may be "removably attached to the BGM by the locking means 31." P. 7, ll. 26-30. As shown in the drawings, the convex surface of the lancet device bears against an outer concave surface of the BGM (which is the same as the outer concave surface of the cap unit 10).

6. In Figure 3 the BGM 30 is attached to the cap unit 10, and the lancet device is attached to the BGM 30. However, the specification discloses that, as an alternative, the BGM 30 may be part of the cap unit 10. P. 6, ll. 21-22.

7. The specification discloses that the BGM 30 would not normally be used without the lancet device 40. P. 8, ll. 5-10. In the case where the BGM is part of the cap unit 10, it would be evident to a person skilled in the art that the lancet device 40 would be removably attached to the cap unit 10, with the convex surface of the lancet device 40 fitting against the concave outer surface of the cap unit 10.

8. Moreover, the specification repeatedly describes the BGM, lancet device, etc. as modular units, that can interchangeably attach to one another. The specification further discloses that, if desired, the cap unit 10 may be used without the BGM. P. 6, ll.

Docket No. 5595.210

30-34. In that case, e.g., if the user had a separate BGM but needed a supply of lancets, the lancet unit would be attached directly to the cap unit 10.

9. As noted above, the BGM or lancet device are attached to the cap unit 10 by way of the locking means 31. In order to "lock" two components together, there must be a mechanical engagement between the two components. That means that either the locking means 31 must include a hook or other such locking element that extends into the interior of the cap unit 10, or the cap unit 10 must include outwardly projecting hooks or similar locking members that extend into the interior of the locking means 31.

10. Were the outwardly projecting hooks or other locking members to be placed on the convex outer surfaces of the cap unit, BGM, and lancet device, such member would dig into the user's hand whenever the device is gripped. Aside from being uncomfortable, having an outwardly projecting hook presents a danger that the device could get caught or cause injury.

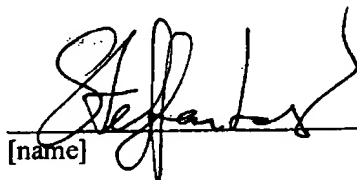
11. In contrast, it would be readily evident to a person skilled in the art that placing the outwardly projecting hooks or other locking members on the concave surfaces would not produce such problems, because the convex surface of the component is not gripped by the user, even while the components are being assembled. Moreover, once the device is assembled, the outwardly projecting hooks or other locking members on the BGM and lancet unit are no longer exposed at all, and there is no danger of the hook member getting caught or causing injury while the assembled device is being used or carried.

Docket No. 5595.210

12. For all of these reasons, a person skilled in the art would understand that the "locking means 31" is an outwardly projecting hook or other locking member that projects into the interior of the device to which it is attached.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2006.02.15


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